BRIAN SANDOVAL
Governor

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

MICHAEL J. WILLDEN
Director

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Administrator

DRUG USE REVIEW (DUR) BOARD

Approved Minutes
April 28, 2011

Las Vegas Chamber of Commerce
6671 Las Vegas Blvd. S., Suite 300
Las Vegas, NV 89119

Nevada State Health Division
4150 Technology Way, Room 300
Carson City, NV 89706

Committee Members Present:
Las Vegas: Paul Oesterman, Pharm.D.; James Marx, MD
Carson City: David England, Pharm.D
Call-In: Steven Rubin, MD
Absent: William Evans, MD; Keith Macdonald, R.Ph.; Chris Shea, Pharm.D.

Others Present:
DHCFP:
Las Vegas: Shannon Richards, Deputy Attorney General
Carson City: Coleen Lawrence, Chief, Program Services; Mary Griffith, Pharmacy Program Specialist

Magellan Medicaid Administration:
Las Vegas: Paula Townsend Pharm.D; Clinical Manager; Shirley Hunting
Carson City: Judy LaFleur

Others:
Las Vegas: Karen Santilla-Astra Zeneca; Damon Cox-Merz; Sandy Sierawski-Pfizer; Steve Fox-GSK; Chris Almedia-Purdue; JoAnn Prevem-GCG
Carson City: Ed Arnold, HP; Rob Earnest-SXC; Mariellen Rich-SXC; Bharat Vashi-HP; Lori Horwarth-Bayer; Sabrina Aery-BMS.

i. Call to Order and Roll Call

Chairman Paul Oesterman called the meeting to order at 1:05 p.m.

Because a quorum of the members was not present at roll call, Chairman Oesterman stated that only non-action items will be addressed until a quorum is present. Agenda item iii. was taken out of order and addressed as the first item of business.

Dr. Marx joined the meeting at 1:14 p.m. Dr. Oesterman announced that a quorum is present.

ii. Discussion and Approval of January 27, 2011 Minutes

MOTION: James Marx motioned to accept the January 27, 2011, minutes as presented.
SECOND: Steven Rubin
VOTES: Unanimous
MOTION CARRIED

iii. Status Update by DHCFP

a. Program Updates

Coleen Lawrence said that key indicator reports are reviewed monthly noting that the pharmacy drug spend has remained flat and the inflation rate continues to be low. On behalf of Chuck Duarte, Administrator, DHCFP, she extended his appreciation to the Board members for their service in helping to accomplish this. Program snapshots will be included in future meeting binders.

Ms. Lawrence announced that Mary Griffith has returned to the DHCFP Program Services and will oversee the Pharmacy and Durable Medical Equipment programs.

Ms. Lawrence stated that in January, 2011, the Medical Management Information System (MMIS) contract was awarded to Hewlett Packard Enterprise Systems (HP). HP has subcontracted the pharmacy benefit management system to SXC Health Solutions. October 1, 2011, will be the transition date from Magellan Medicaid Administration to HP and SXC. HP and SXC will be facilitating the DUR Board and Pharmacy and Therapeutics (P&T) Committee meetings effective with the transition.

iv. Review of Prescribing/Program Trends

a. Top 10 Therapeutic Classes (by Payment and by Claims)

Dr. Townsend reported that antipsychotics continue to maintain the top position as indicated in the report ranked by payment amount for first quarter 2011. Total payment amount in class H7T (antipsychotics excluding Abilify®) has increased approximately 17% with an 11% increase in claims compared to the same period last year; total payment in H7X (Abilify®) has increased 6%. W5D (Synagis®) payment is 32% lower compared to the same period last year which may be attributed to the implementation of criteria based on AAP guidelines recently adopted by the Board.

Dr. Townsend noted that there are two classes in the report which have not been previously reported: P4D (Hyperparathyroid Tx-Vit D Analogs) and C3B (Iron Replacement). These claims consist mainly of physician administered claims (NVPAD claims). The report is a standard canned report which is coded to exclude NVPAD claims from pharmacy reporting. The analytical team is reviewing the report and a corrected version will be presented at the next meeting.

The analgesics, anticonvulsants, anti-anxiety and antipsychotic drugs continue to comprise the top four positions of classes ranked by claims volume.

b. Top 50 Drugs (by Payment and by Claims)

A detailed summary of the above reported information is available in the Top 50 Drugs report.

c. Program Trends

Dr. Townsend reported that recipient enrollment increased in February, 2011, to 87,113 compared to January's count of 85,941. She noted that this is a significant increase compared to February, 2010, when the count was 80,604. Utilizing recipients remains at 40%. 117,558 claims were processed in February, 2011, compared to 126,000 in January, 2011, and 108,000 in February, 2010. February, 2011, claims per user per month have decreased approximately 5% from the previous month. The generic utilization rate is stable at 76.5%.

v. Concurrent Drug Utilization Review (ProDUR)

a. Review of Q1 2011

Dr. Townsend reported that the number of alerts remain consistent with therapeutic duplication occupying the top position in the number of alerts sent to pharmacies; drug-to-age (geriatrics and pediatrics combined) second followed by drug-to-drug and dosing (min/max) alerts.

b. Review of Top Encounters by Problem Type

As requested by the Board, a report was presented breaking down the products in the top alerts per category for the month of March, 2011. Dr. Townsend clarified that the "Alert %" is the percentage of the processed claims for that particular drug which hit the edit.

vi. Retrospective Drug Utilization Review (RetroDUR)

a. Review of Responses

Dr. Townsend reviewed the RetroDUR Letter Response Report by Response Code for the fourth quarter of 2010. The provider response rate was 14% to 19% (15% was the annual review average).

b. Status of Previous Quarter

The RetroDUR Summary Report for calendar year 2010 was presented for Board information.

c. Status of Current Quarter

Dr. Townsend reviewed the RetroDUR Summary Report of new reviews and re-reviews for first quarter 2011.

d. Public Comment

No comment.

e. Discussion and Action by Board for Future Criterion Selection

Dr. Marx asked what the current response process is and what can be done to make it easier for prescribers to respond.

Dr. Townsend stated that the prescriber letters include a response page which can be returned via fax or mail to Magellan.

Dr. England suggested that response by secured email may be another option to increase the response rate.

Ms. Lawrence stated that, in the past, the Board has discussed developing web-based and/or email responses to minimize postal returns, etc.

Dr. Oesterman said that there is the potential for greater response if every possible opportunity is available such as email, web-based as well as faxed or mailed.

MOTION: David England motioned to explore the different routes of prescriber response methods to include electronic notification.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

Dr. Oesterman referred to the response report for criteria "carisoprodol interacts with Opioid Analgesics", October, 2010, noting that ten prescribers responded that "…I did not prescribe the following medications." He asked for clarification on where the information is coming from if the physician states that he is not the source of the prescription.

Dr. Townsend responded that the information included on the RetroDUR profile is based on information submitted by the pharmacy. The prescriber NPI on the incoming claim as entered by the pharmacy may be invalid for that prescriber.

For future criteria selection, Dr. Marx requested a re-run of acetaminophen >4gms per day and Dr. England recommended exploring the top ten black box warnings for review.

There was discussion on the methodology in selecting criteria. Dr. Townsend stated that past criteria has been chosen based on Board input such as compliance issues and drug edits such as skeletal muscle relaxants and anticonvulsants.

Ms. Lawrence proposed developing a plan to address the Board's questions on the methodology of selecting criteria and the focus on future criteria selection. She reminded the Board that, in addition to their recommendations, future criteria will also need to focus on the requirements for the annual DUR report provided to CMS.

Dr. Oesterman requested the proposal be presented at the next meeting.

vii. Presentation of Requested Report on Market Share Shift within Thiazolidinediones (TZD) Class

a. Public Comment

No comment.

b. Discussion and Action by Board on Market Share Shift within Thiazolidinediones (TZD) Class

Dr. Townsend stated that this report is being presented at Board request on the market shift in this class as a result of warning label changes on Avandia®.

The black box warning for Avandia® and Avandamet® states that products containing rosiglitazone can cause or exacerbate congestive heart failure in some patients. If these signs and symptoms develop, heart failure should be managed according to current standards of care; discontinuation or dose reduction must be considered. These agents are not recommended in patients with symptomatic heart failure. A meta-analysis of forty-two clinical studies comparing Avandia® to placebo showed Avandia® to be associated with an increased risk of myocardial ischemic events such as angina or MI. Three other studies comparing Avandia® to other approved oral anti-diabetic medication or placebo have not confirmed or excluded this risk. The available data on the risk of myocardial ischemia are inconclusive. On September 23, 2010, the FDA announced regulatory action to implement restrictions on the use of these products through a program to assure their safe use, Risk Evaluation and Mitigation Strategy (REMS). This program is expected to be approved and formally implemented in spring 2011. Additional safety label changes were made in response to the agency's review of data that suggests an elevated risk of cardiovascular events. The manufacturer, GSK, will be working with the FDA to implement the agency's requirements. Until the REMS program is in place, the FDA's decision allows current or potential users of Avandia® to continue or start using the medication after consultation with the health care professionals about treatment options. The FDA has imposed a new post-marketing requirement for GSK to commission an independent re-adjudication of the endpoints reported in a large prospective randomized control study. Healthcare providers will be required to enroll in the REMS program in order to prescribe rosiglitazone containing products; patients must be enrolled in the program by their physicians to begin or continue treatment. Pharmacists will be required to be enrolled in order to dispense rosiglitazone containing products. February 3, 2011, the FDA announced that rosiglitazone containing products' package insert and patient medication guides

have been updated to include the cardiovascular risk associated with the drug including myocardial infarction. The updated labeling suggests that these drugs should only be used in patients currently being treated with these medications and those whose blood sugar cannot be controlled with other anti-diabetic medications.

Dr. Townsend presented the market shift report for these products. The reporting period is February, 2009, through January, 2011, and provides the number of claims per quarter for each agent and the percentage for the market basket which includes rosiglitazone containing products and combinations. About half of the claims that fall within the Advandia® and Advandamet® group are third party liability claims (Medicare/Medicaid dual eligibles) which are not driven by the Preferred Drug List (PDL).

Dr. Oesterman commented that the report shows a significant ongoing reduction of the utilization of the rosiglitazone containing products which lowers the risks associated with the side effect profile of these medications. He asked for Board consideration to recommend to the P&T Committee the removal of rosiglitazone containing products from the PDL.

MOTION: David England motioned to request that the P&T Committee consider the status of rosiglitazone containing products on the PDL.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

viii. Presentation of Updated Medicaid Services Manual Chapter 1200: Prescription Drugs

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Updated Medicaid Services Manual Chapter 1200: Prescription Drugs

Mary Griffith stated that Chapter 1200 is being reformatted to be more user-friendly for prescribers, pharmacies and recipients. In reviewing other states' online policy manuals, the new format may include links provided within the manual for direct access to PA criteria, drug limitation quick guides, etc. Board members with suggestions can forward them to Ms. Griffith.

Ms. Lawrence reminded the Board that due to the governor's executive order which placed a freeze on new policy changes, recommendations from the last two DUR Board meetings were placed on hold. DHCFP has since received an exception for pharmacy policy and the proposed changes from the previous two meetings as well as this meeting will be presented at the next scheduled public hearing. Chapter 1200 formatting changes will be presented at the subsequent public hearing. She stated that this item does not require Board action but the Board is being solicited for comments and suggestions.

Dr. Oesterman thanked DHCFP on behalf of the Board stating that all practitioners will appreciate any attempts at making Chapter 1200 more user-friendly. He asked that Board members forward recommendations to Ms. Griffith and that this item be agendized for discussion at the next meeting.

Dr. England asked regarding pharmacist access to electronic health records to determine if a recipient meets criteria. Ms. Lawrence replied that this is in the development process through the DHCFP electronic health record specialist and offered his participation at future meetings.

Dr. Oesterman requested the specialist attend the next meeting.

ix. Proposed Removal of Prior Authorization Criteria for ramipril (Altace)

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of proposed removal of clinical prior authorization criteria for ramipril (Altace).

Dr. Townsend stated that PA criteria for ramipril were put in place due to demand for this ace inhibitor (ACE) following publication of the Heart Outcomes Prevention Evaluation Study (HOPE). The HOPE Study followed high risk patients over age 55 either with a history of coronary artery disease, stroke or peripheral vascular disease or with diabetes and at least one other risk factor. In this study, Altace® was compared with vitamin E or placebo treatment. Following 4.5 years of treatment, 3% of patients taking ramipril died from sudden cardiac death or experienced a non-fatal cardiac arrest compared with 4% taking placebo. This translated to a 21% reduction in unexpected deaths, deaths due to cardiac arrest or non-fatal cardiac arrest for those taking Altace®. The results stressed the importance of prescribing an ACE inhibitor in patients at high risk of developing heart disease and stroke. The study was conducted with ramipril, which at the time was only available as the branded product, Altace®. There were numerous other generic ACEs within the marketplace available at that time. The intent was to have Altace® available for this indication but that other available ACE inhibitors should be used for other indications such as treating hypertension. PA criteria were put in place to ensure that Altace® was available for patients meeting criteria. Ramipril is now available generically. The PA criteria are still in effect because the criteria apply to the drug and not specifically to the brand. There are currently 129 claims per quarter requiring PA for ramipril which are filled with the generic product. It is the recommendation of DHCFP and Magellan Health that the current PA criteria be removed for ramipril.

MOTION: James Marx motioned to remove the prior authorization criteria for ramipril.
SECOND: David England
VOTES: Unanimous
MOTION CARRIED

x. Update on Prior Authorization Criteria for Cox II Inhibitors (Celebrex®)

a. Public Comment

Sandy Sierawski, Pfizer, spoke in support of Celebrex®. Celebrex® was granted an accelerated approval in 1999 by the FDA for Familial Adenomatous Polyposis (FAP) to reduce the number of adenomatous colorectal polyps and familial adenomatous polyposis. Because approval was conditional, Pfizer was required to provide additional surrogate input point data on the reduction of the number of polyps. Trials are being run, but because FAP is an extremely rare disease, enrollment is slower than expected. Pfizer has not been able to provide the additional data required by the FDA and has voluntarily removed the FAP indication from Celebrex®. The removal of the FAP indication is not due to any new efficacy or safety data that alters the benefit risk profile of Celebrex®.

b. Discussion and Action by Board on the Update Prior Authorization Criteria for Cox II Inhibitors (Celebrex)

Dr. Townsend stated that the current criteria include the indication for FAP and a quantity limit of 800mg/day due to FAP high dose. The FAP indication has been removed from the proposed criteria being presented and the quantity limit changed to 400mg/day which is the maximum dose recommended for the other indications.

MOTION: David England motioned to approve the proposed criteria as presented.
SECOND: James Marx
Dr. Marx asked if patients currently on 800mg/day will be no longer be authorized or can an override be granted.
Dr. Townsend stated that the authorization for the current PA is a year from the date of approval. Patients who currently have a PA will continue until the PA end date.
Dr. Marx asked how many recipients are currently on the higher dose.
Dr. Townsend replied that there are very few recipients on the higher dose. A report will be presented at the next meeting.
VOTES: Unanimous
MOTION CARRIED

xi. Proposed Prior Authorization Criteria for 17-alphahydroxyprogesterone caproate (Makena™)

a. Public Comment

No comment.

b. Discussion and Action by Board on the Prior Authorization Criteria for 17-alphahydroxyprogesterone caproate (Makena™)

Ms. Lawrence read the FDA Statement on Makena™, release date March 30, 2011. On February 3, 2011, the FDA approved Makena® (hydroxyprogesterone caproate) for the reduction of the risk of preterm birth in women who have a history of spontaneous preterm birth. Makena™ is a synthetic progestin hormone and a derivative of 17-alpha-hydroxyprogesterone (17-P). 17-P has been available to patients for many years provided by compounding pharmacies. The manufacturer of Makena™, KV Pharmaceuticals, sent a letter to compounding pharmacies telling them that the FDA would enforce the company's exclusive right to make the drug, which was not correct. As stated in the FDA Statement, "…In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products." She referenced the American Congress of Obstetricians and Gynecologist (ACOG) statement released on April 1, 2011, which indicates that although KV Pharmaceuticals reduced the price of Makena™ from $1,500 per dose to $690 per dose, the price is still prohibitively high compared to 17-P (cost of the injectable compound is approximately $20/dose). There is no evidence that Makena™ is more effective or safer than the compounded product. FDA approval for Makena™ relied on data using the compounded product. ACOG "applauded" the FDA for allowing compounding pharmacies to continue to produce 17-P.

Ms. Lawrence stated that effective January 1, 2011, 17-P was removed from the CMS Drug Rebate Program therefore no longer reimbursed by Nevada Medicaid. Makena™ is currently on the CMS list of rebateable products and covered by Nevada Medicaid. The clinical criteria being proposed is based on the manufacturer's package insert (PI) for Makena™ and not on cost.

Dr. Townsend said that the drug review for Makena™ is included in the meeting binder as well as the web address to access the pivotal trial supporting the approval of Makena™. Makena™ is indicated to reduce the risk of preterm birth in women with a singleton pregnancy and history of singleton spontaneous preterm birth. It's not indicated for multiple gestations or in women with other risk factors. The pivotal study conducted in 2002, used a compounded 17-P product. Compared to controls, the proportion of women who delivered preterm (defined as <37 weeks) was reduced to 37.1% with 17-P vs. 54.9% for controls. The treatment difference was 17.8% and the estimated number-needed-to-treat was 5 to 6 women, meaning you need to treat 5 or 6 women to prevent one preterm birth. The proportion of women who delivered preterm <35 and <32 weeks were also statistically significantly lower but the confidence interval in these two groups was close to zero. The NNT to prevent one delivery at 32 weeks was 12. Other secondary endpoint results are summarized in the new drug review in the binder. The proposed PA criteria follow the clinical

trial population for which the benefit has been demonstrated and is also consistent with what other state MCOs require for this drug.

Dr. Rubin asked if there is a compound generic equivalent available. Dr. Townsend replied that the powered product is available for compounding; however, because the manufacturer does not participate in the CMS Drug Rebate Program, it is not reimbursable by Nevada Medicaid.

Ms. Lawrence stated that prior to the release of Makena™, most providers were not billing Medicaid for 17-P. The issue arose when KV Pharmaceuticals released the letter. Providers can continue their practice of using the generic 17-P compounded product utilizing the resources for funding which they were accessing before. Makena™ is an option for the providers and currently reimbursable by Nevada Medicaid therefore clinical criteria is being proposed for this product.

The Board discussed including a statement in the criteria that the physician acknowledges that 17-P is an option though not reimbursable by Medicaid and references the FDA and CMS letters; time-limited PAs were also discussed. Dr. Oesterman commented that the consensus of the Board appears that they are not pleased with the manufacturer of Makena's activities and knowing that there is an alternative that is effective and less expensive. He asked what the process is to get the generic product reimbursable.

Ms. Lawrence stated that DHCFP will explore reimbursement of the compounded product through the home health benefit. Because of the transition to the new vendor, the system modification is not an option at this time. A web announcement to practitioners will be posted promoting the use of the generic product which supports the FDA statement.

Dr. Rubin commented that the suggestions are good and felt that this is an opportunity to revise policies and procedures across the board because of the current economic time when states cannot afford to allow "intruders" to continue siphoning valuable dollars. Pharmaceutical company rebates does not seem like justification for a $700 payment versus $20. He proposed that the DUR Board not have clinical criteria at this time because he is not willing to endorse this type of activity.

Dr. Marx stated that providers are not being reimbursed for the 17-P and being reimbursed for Makena™. The unintended consequences are that physicians willing to provide this service are going to become scarce. As a result, these patients will go to clinics and the State will pay full cost. He felt that Magellan and DHCFP should provide strong feedback to CMS regarding the drug rebate regulation and voice concerns to the public as well. The drug rebate should be irrelevant when hundreds of dollars are being squandered on each dose of this medication. He felt the Board should move forward with the PA criteria.

MOTON: **James Marx motioned to approve the prior authorization criteria for Makena™ as presented. DHCFP and Magellan to provide feedback to CMS regarding the Board's position on the drug rebate regulation.**
SECOND: **David England**
Dr. Rubin asked if the criteria include a justification or contraindication to using the generic alternative.
Dr. Townsend replied that the criteria does not include a statement of failure or have a reason that a product cannot be used for which there is no reimbursement in order to get the product which can be reimbursed.
Dr. Rubin asked why failure of the generic equivalence does not apply to this medication?
Dr. Townsend said that the drug (17-P) is not a generic of Makena™; it is a compound.
Dr. Rubin offered a friendly amendment that the criteria include that the recipient is not eligible for a compound equivalent.
The friendly amendment was not accepted.
AYES: **England, Marx, Oesterman**
NAYES: **Rubin**
MOTION CARRIED

Dr. Oesterman reminded the Board that the criteria can be reviewed again at a future meeting. He requested utilization data be presented at the next meeting.

xii. Presentation of Recipient Outreach Programs: Review of Draft Web Announcement on Acetaminophen Dosage Limits

a. Public Comment

No comment.

b. Discussion and Action by Board on Draft Web Announcement on Acetaminophen Dosage Limits

At Board request, Dr. Townsend presented a draft web announcement on acetaminophen dosage. The draft summarizes the acetaminophen dosing issue and includes information regarding the FDA's request that manufacturers limit the amount of acetaminophen containing products to 325mg per dose. The announcement summarizes the FDA position statements and documents posted on their website.

The Board discussed converting the document to a bullet point format; moving the synopsis (last paragraph) to the beginning; highlighting the Board's recommendation; using the term "acetaminophen" versus "APAP" per FDA recommendation; include a statement regarding monitoring hepatic function in patients on >4gm per day; referencing studies.

Dr. Oesterman commented that the draft is a good start on the general concept. He offered to convert the document to a bullet point format and email a draft to the Board members for review and comment. The final draft will be presented at the next meeting.

xiii. Presentation of Recipient Outreach Programs: Smoking Cessation Programs

a. Public Comment

No comment.

b. Discussion by Board on Recipient Outreach Programs: Smoking Cessation

Ms. Lawrence stated that DHCFP has created a partnership with the American Lung Association and the school of medicine in Las Vegas. A representative from the Lung Association will be invited to present information on co-branding outreach materials for smoking cessation for Nevada Medicaid and Nevada Check-up recipients at a future meeting.

xiv. Presentation of Requested Report on Utilization and Cost of Proton Pump Inhibitors (PPIs) and H2 Receptor Blockers

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Report on Utilization and Cost of Proton Pump Inhibitors (PPIs) and H2 Receptor Blockers

Dr. Townsend stated that at the last meeting, the Board noted that a high percentage of PA requests for PPIs were being approved. She presented a utilization report for calendar year 2010. There were 5,000 more claims for H2s versus PPIs indicating that H2s are being prescribed more frequently.

Dr. Oesterman commented that the report addresses the Board's questions and Board action is not required.

xv. Presentation of List of Outstanding DUR Board Report Requests

Ms. Lawrence stated that this report tracks open action items requested by the Board and will be provided at each meeting.

xvi. Public Comment

No comment.

xvii. Date and Location of Next Meeting

The next meeting is scheduled for July 28, 2011, at the Las Vegas Chamber of Commerce with videoconferencing to the Nevada State Health Division in Carson City

xviii. Adjourn

Chairman Oesterman adjourned the meeting at 3:23 p.m.